

Remarks

Claims 1-8, 10-25, and 27-32 are pending. Claims 9 and 26 are canceled by this communication. Claims 1-8, 10-25, and 27-32 are rejected.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-5, 8, 17 and 22-25 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient support in the specification. In particular, the Examiner asserts that the number of polymers is limited as to not be commensurate with the scope of the claimed subject matter, which recites a polymer having a glass transition temperature (T_g) of about – 50 °C or less and an additive having a T_g of about – 50 °C or greater.

The written description requirement for a claimed genus can be “satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings ..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties...” (see, e.g., Reagents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997)). Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces (see, e.g., In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993), and In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)).

Independent claims 1 and 17, and claims dependant therefrom, recite a coating which includes a first polymer having a glass transition temperature (T_g) of about – 50 °C or less and an additive that can be a polymer having a T_g of about – 50 °C or greater.

The specification provides sufficient description of the claims. At pages 5, 10, and 11, the description provides a coating having a first polymer having a T_g of about – 50 °C or less and

an additive that can be used can be a polymer having a T_g of about – 50 °C or greater, a physical characteristics that is either published or can be readily ascertained by a simple test. The specification at pages 5 and 10-13 provides a large number of exemplary species for the first polymer and for the additive. A person of ordinary skill in the art therefore can readily recognize a polymer having a T_g of about – 50 °C or less and an additive having a T_g of about – 50 °C or greater as described by the specification. Applicants respectfully submit that the specification provides sufficient description of claims 1-5, 8, 17 and 22-25 under 35 U.S.C. §112, first paragraph.

Claims 1-5, 8, 17 and 22-25 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Examiner alleges that the first polymer having a T_g of about – 50 °C or less and an additive having a T_g of about – 50 °C or greater can reach through the claims to polymers not yet synthesized. Applicants respectfully fail to see how this assertion, even if it were true, could support the Examiner's allegation that claims 1-5, 8, 17 and 22-25 lack enablement.

A proper test of enablement is whether the specification provides sufficient guidance to allow a person of ordinary skill in the art to practice the claimed subject matter without undue experimentation (see, Graham v. John Deere Co., 383 U.S. 1 (1966)). As discussed above, a person of ordinary skill in the art would recognize that the T_g of a polymer is either known or can be readily ascertained by a simple test, a task that is commonly carried out by laboratory technicians. Therefore, there is no “undue experimentation” for a person of ordinary skill in the art to choose a polymer having a T_g of about – 50 °C or less and an additive having a T_g of about – 50 °C or greater to make and use the subject matter defined by the claims.

Applicants respectfully submit that claims 1-5, 8, 17 and 22-25 are fully enabled under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 10 and 27 are rejected as being indefinite under 35 U.S.C. §112, second paragraph. The Examiner alleges that these claims define 3-PHB as an additive, which is inconsistent with the Examples. Applicants respectfully direct to the Examiner to Examples 5-8, which describe forming a coating including polycaprolactone (PCL) (a first polymer) and 3-PHB (additive). As control, examples 1-4 describes forming a coating including only PCL or 3-PHB. Claims 10 and 27 therefore are consistent with the description in the Examples and clear and definite.

Claims 12-14, and 29-31 are rejected as being indefinite under 35 U.S.C. §112, second paragraph. Applicants believe the amendments to the claims render these rejections moot.

Rejections under 35 U.S.C. § 102

Claims 1-8, 10, 11, 15-25, 27, 28 and 32 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. application publication No. 2004/0181271 by DeSimone et al. ("DeSimone").

Claim 1 defines a medical article comprising an implantable substrate having a coating. The coating comprising a first biologically erodable polymer having a glass transition temperature below about -50°C and a biologically erodable polymeric additive mixed with the first polymer. **The polymeric additive has a degree of crystallinity greater than that of the first polymer.** As a person of ordinary skill in the art would recognize, degree of crystallinity is an important parameter of a polymeric material, which can be different for a polymer and depend upon the conditions under which the polymer is made and processed.

DeSimone describes that a coating can be formed on an intraluminal prosthesis, which can include blends of PCL, and PHB, etc. However, DeSimone does not provide the element that the polymeric additive has a degree of crystallinity greater than that of the first polymer in the coating, which, as discussed above, is an important parameter of the first polymer and the polymeric additive recited in claim 1. Therefore, claim 1 is patentably allowable over DeSimone under 35 U.S.C. §102(e). Claims 2-8, 10, 11, 15 and 16 depend from claim 1 and are patentably allowable over DeSimone under 35 U.S.C. §102(e) for at least the same reason.

Claim 17 defines a method of forming a coating. The coating comprises a first biologically erodable polymer having a glass transition temperature below about -50°C and a biologically erodable polymeric additive mixed with the first polymer. The polymeric additive has a degree of crystallinity greater than that of the first polymer. As the above discussion shows, DeSimone fails to provide for this important feature of the coating formed by the method of claim 17. Therefore, claim 17 is patentably allowable over DeSimone under 35 U.S.C. §102(e). Claims 18-25, 27, 28 and 32 depend from claim 17 and are patentably allowable over DeSimone under 35 U.S.C. §102(e) for at least the same reason.

Claims 1-8, 10-25 and 27-32 are rejected as being anticipated by EP 0970,711 A2 to Hossainy et al. ("Hossainy").

Hossainy describes a process for coating a stent. The coating can include a polymer such as PCL, PHB, PHV PGA, etc., and blends thereof. However, Hossainy does not provide the element that the polymeric additive has a degree of crystallinity greater than that of the first polymer in the coating, which, as discussed above, is an important feature of claim 1.

Therefore, claim 1 is patentably allowable over Hossainy under 35 U.S.C. §102(b). Claims 2-8

and 10-16 depend from claim 1 and are patentably allowable over Hossainy under 35 U.S.C. §102(b) for at least the same reason.

As discussed above, claim 17 defines a method of forming a coating including a first biologically erodable polymer having a glass transition temperature below about -50°C and a biologically erodable polymeric additive mixed with the first polymer. **The polymeric additive has a degree of crystallinity greater than that of the first polymer.** For the reasons discussed above, claim 17 is patentably allowable over Hossainy under 35 U.S.C. §102(b). Claims 18-25 and 28-32 depend from claim 17 and are patentably allowable over Hossainy under 35 U.S.C. §102(b) for at least the same reason.

Claims 1-4, 11, 16-21, 28 and 32 are rejected as being anticipated under 35 U.S.C. 102(b) by U.S. application publication No. 2001/0014717 by Hossainy ("Hossainy 2").

Hossainy 2 describes a coating that can include, among others, PCL, and PHB. However, Hossainy 2 does not provide that the coating can include a first polymer and a polymeric additive where **the polymeric additive has a degree of crystallinity greater than that of the first polymer, an important feature shared by independent claims 1 and 17.** As such, independent claims 1 and 17 are patentably allowable over Hossainy 2 under 35 U.S.C. §102(b). Claims 2-4, 11, and 16, which depend from claim 1, and claims 18-21, 28 and 32, which depend from claim 17, are all allowable over Hossainy 2 under 35 U.S.C. §102(b) for at least the same reason.

Rejections under 35 U.S.C. 103

The Office Action at page 6, the second paragraph from the bottom indicates that claims are rejected under 35 U.S.C. §103(a) as being obvious over DeSimone but does not set forth

which claim(s) is rejected. Applicants assume the Examiner rejects all the pending claims, claims 1-8, 10-25, and 27-32, as being obvious over DeSimone.

As discussed above, the two independent claims, claims 1 and 17, both recite a coating comprising a first polymer and a polymeric additive. **The polymeric additive has a degree of crystallinity greater than that of the first polymer**. As a person of ordinary skill in the art would appreciate, the degree crystallinity of a material forming a coating will have a direct effect on the coating properties, e.g., mechanical properties (e.g., strength properties and water uptake properties) and degradation rates of the coating. DeSimone clearly fails to teach this important limitation of the coating as recited in claims 1 and 17. Therefore, claims 1 and 17 are patentably allowable over DeSimone under 35 U.S.C. §103(a). Claims 2-8, and 10-16, which depend from claim 1, and claims 18-25 and 27-32, which depend from claim 17, are patentably allowable over DeSimone under 35 U.S.C. §103 for at least the same reason.

Claims 1-8, 10-25, and 27-32 are also rejected under 35 U.S.C. §103(a) as being obvious over Hossainy 2 in view of DeSimone.

As mentioned above, claims 1 and 17 both recite a coating comprising a first polymer and a polymeric additive. **The polymeric additive has a degree of crystallinity greater than that of the first polymer**. The above discussions show that both Hossainy 2 and DeSimone fail to teach this important feature of the coating. Therefore, claims 1 and 17 are patentably allowable over Hossainy 2 in view of DeSimone under 35 U.S.C. §103(a). Claims 2-8, and 10-16, which depend from claim 1, and claims 18-25 and 27-32, which depend from claim 17, are patentably allowable over Hossainy 2 in view of DeSimone under 35 U.S.C. §103 for at least the same reason.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSIONS

Withdrawal of the rejection and allowance of the claims is respectfully requested. If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned for approval of an Examiner's amendment. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,



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